

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA
AT CLARKSBURG**

GILEAD SCIENCES, INC. and
EMORY UNIVERSITY,

Plaintiffs,

V.

Case No. 1:14-cv-99-IMK-JSK

MYLAN INC. and
MYLAN PHARMACEUTICALS INC.,

Defendants.

**DEFENDANTS MYLAN INC. AND MYLAN PHARMACEUTICALS INC.'S
OPPOSITION TO PLAINTIFFS' OBJECTIONS TO MAGISTRATE JUDGE KAULL'S
ORDER/OPINION DENYING MOTION TO COMPEL DOCUMENTS**

Defendants Mylan Inc. and Mylan Pharmaceuticals Inc. (collectively, “Mylan”) hereby submit their Opposition to Plaintiffs Gilead Sciences, Inc. and Emory University (collectively, “Plaintiffs”) Objections to Magistrate Judge Kaul’s Order/Opinion Denying Motion to Compel Documents.

I. INTRODUCTION

In their Objections to Magistrate Judge Kaull’s Order, Plaintiffs effectively ask this Court to ignore well-settled canons of patent law and to forgive their six-month delay in moving to compel the documents at issue. The Court should decline the invitation.

Under Local Rule of Civil Procedure 37.02(b), Plaintiffs were required to move to compel within 30 days of receiving Mylan's relevancy objections to Plaintiffs' document requests documents seeking the PEPFAR materials now at issue.¹ To excuse its nearly six month

¹ PEPFAR is an abbreviation for the U.S. President's Emergency Plan for AIDS Relief. PEPFAR represents the U.S. Government's initiative to help save the lives of those suffering from HIV/AIDS around the world. "This

delay, Plaintiffs assert that they had no basis to know that Mylan's PEPFAR materials may be relevant to the litigation. By making that assertion, Plaintiffs tacitly admit that their document requests seeking Mylan's PEPFAR materials had no basis at the time Plaintiffs made the requests. Plaintiffs further assert that they did not appreciate the potential relevance of Mylan's PEPFAR product until June of this year, when the details of the enablement issue were "fully articulated." There is no explanation as to how Plaintiffs needed "full articulation" and was unable to appreciate the enablement issue, given that Mylan expressly pleaded enablement in its Answer, and also explicitly identified the defense in Mylan's invalidity contentions. The Magistrate Judge, therefore, did not abuse his broad discretion or commit clear error in finding that Plaintiffs had failed to show good cause for making an exception to the Local Rules of this Court.

Moreover, the Magistrate Judge was not "clearly erroneous" in his alternative ground for denying the motion: the conclusion that Mylan's PEPFAR product is irrelevant to whether the patent-in-suit was enabled by the disclosures in the patent. Plaintiffs' failed motion to compel sought documents relating to a Mylan product that is intended for use solely in developing countries struggling to combat the HIV/AIDs epidemic. Plaintiffs correctly point out that "undue experimentation" is an aspect of the enablement assessment, but fail to cite to any authority holding that products developed by the accused infringer (here, Mylan) years after the filing of Plaintiffs' patent application could somehow be relevant to this inquiry. There is no such authority. The enablement inquiry is necessarily focused on whether the patent claims are enabled by Plaintiffs' patent application, measured as of the time the application was filed with the U.S. Patent and Trademark Office ("PTO").

historic commitment is the largest by any nation to combat a single disease internationally, and PEPFAR investments also help alleviate suffering from other diseases across the global health spectrum." *See* The United States President's Emergency Plan for AIDS Relief, <http://www.pepfar.gov/about/index.htm> (visited July 28, 2015).

Thus, the relevant question is the level of experimentation needed to make the product in accordance with the disclosure contained in the patent. There is no relevance to the level of experimentation needed to make another product (whether that is the accused product or Mylan's PEPFAR product). What a person skilled in the art could do in light of the patent's disclosure and the knowledge of that hypothetical person is not changed by later activities of the accused infringer. There is no error, much less clear error, in the ruling. Thus, even a timely motion would have been properly denied by the Magistrate Judge.

Plaintiffs' argument not only vitiates U.S. patent law, it also defies common sense. Hypothetically speaking, *if Plaintiffs' position were the law, then no patent could ever be found invalid for lack of enablement*, because the mere fact that someone else (*e.g.*, the accused infringer) was able to make their own product at some point after the patent application was filed would show that the patents enabled others to make and use the invention. The fact that 35 U.S.C. § 112 even exists proves that Plaintiffs' relevancy argument is wrong. The fact that no U.S. court has ever adopted Plaintiffs' argument is further evidence that their position is untenable, to say the least.

In view of Plaintiffs' delay in bringing their motion to compel, and the irrelevance of the documents at issue, Magistrate Judge Kaull correctly denied Plaintiffs' motion to compel. Accordingly, Plaintiffs' Objections to Magistrate Judge Kaull's Order should be rejected.

II. BACKGROUND

The parties fully briefed the factual and procedural background surrounding their dispute in their respective motion to compel and opposition filings, and for sake of brevity will not be repeated here. *See* Dkt Nos. 160, 176, and 183. After receiving these materials, Magistrate Judge Kaull conducted an in-person hearing on June 29, 2015.

III. STANDARD OF LAW

The general standard for review of magistrate judge decisions on non-dispositive motions, such as discovery motions, has been succinctly summarized by this court:

As to nondispositive pretrial matters, a magistrate judge's ruling may be reversed only on a finding that the order is "clearly erroneous or contrary to law." Fed. R. Civ. P. 72(a); 28 U.S.C. § 636(b)(1). "A finding is 'clearly erroneous' when although there is evidence to support it, the reviewing court on the entire evidence is left with a definite and firm conviction that a mistake has been committed." *United States v. United States Gypsum Co.*, 333 U.S. 364, 395 (1948). In light of the broad discretion given to a magistrate judge in the resolution of nondispositive discovery disputes, the court should only overrule a magistrate judge's determination if this discretion is abused. *Detection Sys., Inc. v. Pittway Corp.*, 96 F.R.D. 152, 154 (W.D.N.Y.1982).

Shoop v. Hott, 2010 WL 5067567, at *2 (N.D.W. Va. 2010). The decision of Magistrate Judge Kaull in this case concerned a discovery matter for which magistrate judges generally have broad discretion. The decision also concerned whether there was an adequate basis to forego applying the provisions of the Local Rules of this Court requiring a party to file any discovery motion within 30 days, absent a showing of "excusable neglect" or "action of the non-moving party." L.R. Civ. P. 37.02. In such cases, this Court expressly imposes the burden on the objecting/appealing party to show "clear error." *Myers v. Reason*, 2007 WL 81891, at *3 (N.D.W. Va. 2007) (upholding decision of magistrate judge that motion to compel was untimely because a review of the record did not create "the kind of definite and firm conviction that a mistake has been committed necessary to reverse the ruling of the magistrate judge.").

IV. ARGUMENT

A. Magistrate Judge Kaull Correctly Determined That Plaintiffs' Motion To Compel Is Time Barred

Plaintiffs have failed to provide any credible explanation for their substantial delay in bringing their motion to compel. The implicit position of Plaintiffs, namely, that they first

discovered the alleged relevance of Mylan's PEPFAR product in June of this year, was properly rejected by the Magistrate Judge. Accordingly, there was no "clear error" in light of the Plaintiffs' implausible theory that, when they initially served Mylan with PEPFAR-related document requests back in 2014, that those requests had no relevance to the litigation when served. For this reason alone, Plaintiffs' Objections must be rejected.

The Northern District of West Virginia Civil Local Rules state that:

A motion to compel, or other motion in aid of discovery, is deemed waived if it is not filed within thirty (30) days after the discovery response or disclosure requirement sought was due, which date is determined in accordance with a rule or by mutual agreement of the parties, unless such failure to file the motion was caused by excusable neglect or by some action of the non-moving party. In any event, the moving party must show good cause to delay the trial or modify the scheduling order.

N.D. W. Va. L.R. Civ. P. 37.02(b). Plaintiffs were first put on notice that Mylan was pursuing a lack of enablement defense to the patents at issue when Mylan answered the Complaint back on August 12, 2014—well before written discovery even commenced. Thereafter, Plaintiffs served Mylan with requests for the production of documents and things, which included specific requests for the PEPFAR-related documents that were at issue in Plaintiffs' rejected motion to compel.² Mylan served its objections to those requests on December 22, 2014. Those objections indicated that Mylan would only be producing materials related to its ANDA product at issue in the litigation, and that Mylan would not be producing for other products (*e.g.*, PEPFAR products), citing relevancy, among other objections. *See* Dkt No. 160-1, Mylan's Objections and Responses to Plaintiffs' First Set of Requests for Production (Nos. 1-101), at Nos. 5, 10, 20, 24, and 44 (specifically refusing to produce the PEPFAR documents) and Nos. 3, 13, 21, 22, 37, 40,

² Plaintiffs' request for the PEPFAR-related documents roughly 8 months ago, belies Plaintiffs' current claim that they could not have anticipated the alleged relevance of these documents. In fact, it proves that in November 2015, Plaintiffs already knew enough about the Mylan's defenses to specifically request the PEPFAR-related documents at that time.

48, 58, and 60 (refusing to produce documents relating to products that are not the subject of the ANDA at issue in this litigation).

Plaintiffs' time to file a motion to compel for documents that Mylan refused to produce began to run no later than December 22, 2014. *See* N.D. W. Va. L.R. Civ. P. 37.02(b). However, it was not until May 27, 2015, six months later, that Plaintiffs first indicated that they were opposing any of Mylan's refusals to produce documents in response to Plaintiffs' Requests. Under the Local Rules, Plaintiffs had **30 days** to file a motion to compel, instead Plaintiffs waited **158 days** to file. Plaintiffs' lengthy delay in filing their Motion to Compel is a waiver of their right to compel such production. *See Gilbert v. Advance Stores Co., Inc.*, C.A. No. 1:13-cv-261, 2014 U.S. Dist. LEXIS 146155, at *5-6 (N.D. W. Va. Oct. 14, 2014) (finding that plaintiffs had "waived [their] right to any material [they] may have obtained from the request" to compel because they delayed over 70 days in filing their motion to compel.)

Plaintiffs assert but a single basis for their claim that Mylan's PEPFAR product is relevant to this litigation: that it might be relevant to the "undue experimentation" element of the enablement inquiry. That theory is in error (as will be discussed below), but it is the sole basis for the argument of Plaintiffs that "excusable neglect" or the "some action of the non-moving party" excuses compliance with the Local Rules. N.D.W. Va. L.R. Civ. P. 37.02(b). Plaintiffs, however, expressly requested Mylan's PEPFAR ANDA, and Mylan expressly refused to provide it nearly six months prior to the motion. Plaintiffs' effort to excuse their delay is that they had no reason to know their request was relevant to Mylan's invalidity defense, or to any other issue in the case, until Mylan "fully articulated its non-enablement undue experimentation defense" in June of 2015. *See* Plaintiffs' Objections (Dkt. No. 195) at 5. Were that true, Plaintiffs would be admitting that their PEPFAR request had no basis at the time it was made. Were the request

relevant at the time it was made, Plaintiffs’ motion would be untimely. Therefore, Plaintiffs implicitly asked the Magistrate Judge to accept that the request for the PEPFAR ANDA was not originally for relevant documents, but became relevant fortuitously and in an unforeseen way, only when Mylan “fully articulated” the details of the enablement issues that are a part of its invalidity defense. Plaintiffs further asked the Magistrate to accept that they could not foresee the relevance of their own request—not because the request actually lacks relevance (as it does) but because they just did not foresee any enablement issue. Magistrate Judge Kaull was well within the scope of his discretion, and was committing no “clear error,” when he declined to accept the profound implausibility of Plaintiffs’ claim that they did not know of any theory of relevance to their request.

B. Magistrate Judge Kaull Correctly Determined That The Materials At Issue Are Not Relevant To Enablement

Enablement in the patent context examines the relationship between the patent application as filed, the claims of the patent as issued and the knowledge of those skilled in the art *as of the patent application’s filing date* with the U.S. Patent and Trademark Office. *National Recovery Techs., Inc. v. Magnetic Separation Sys., Inc.*, 166 F.3d 1190, 1196 (Fed. Cir. 1999). Mylan’s development of its PEPFAR product—which occurred years after the patent application at issue was filed, which was intended for sale outside the United States, and which differs from the composition of the Mylan product accused of infringement in this case—is wholly irrelevant to this inquiry, for multiple reasons.

First, it is blackletter law that an accused infringer’s product is legally irrelevant to the legal issue of enablement. The Court of Appeals for the Federal Circuit has stated on multiple occasions that the accused product is not relevant to enablement. *See, e.g., Durel Corp. v. Osram Sylvania Inc.*, 256 F.3d 1298, 1306 (Fed. Cir. 2001) (“The dispositive issue of

enablement does not turn on whether the accused product is enabled.”) (quoting *Genentech, Inc. v. Novo Nordisk, A/S*, 108 F.3d 1361, 1365 (Fed. Cir. 1997)). This area of the law is well-settled. See, e.g., *Personalized Media Comm., LLC v. Zynga, Inc.*, No. 2:12-cv-00068-JRG-RSP, 2013 WL 5962812, at *2 (E.D. Tex. Nov. 7, 2013) (excluding from trial expert testimony relating to enablement because it improperly relied on the accused device); *Pfizer Inc. v. Teva Pharm. USA, Inc.*, 882 F. Supp. 2d 643, 682 (D. Del. 2012) (stating that enablement focuses on the patent application, as filed, and not on the accused product).

Second, Mylan’s PEPFAR product is different from the Mylan product accused of infringement in this case. To be sure, Mylan’s PEPFAR product is not even accused of infringement here, nor could it be. Mylan’s PEPFAR product is directed to developing countries struggling to contain the HIV/AIDs epidemic, not the United States market. Because Mylan’s PEPFAR product is not at issue in this case, Plaintiffs’ relevancy argument regarding that product is even weaker than the failed enablement arguments made by other litigants that were, at least, focused on the actual accused device at issue in those cases.

Third, there is no question that Mylan’s PEPFAR-related documents were generated by Mylan years after the relevant time point for evaluating enablement. This fact alone precludes their relevance to the legal issue of enablement, which is measured as of the time Plaintiffs’ filed their patent application.

The following excerpt from the Court of Appeals for the Federal Circuit highlights one of the many errors plaguing Plaintiffs’ argument:

The district court considered whether certain terms would have been enabling to the public and looked to formula developments and publications occurring well after [the inventor’s patent application] filing date in reaching its conclusions under § 112. Patents, however, are written to enable those skilled in the art to practice the invention, not the public, and § 112 *speaks as of the application filing date, not as of the time of trial.*

W.L. Gore & Assoc., Inc. v. Garlock, Inc., 721 F.3d 1540, 1556 (Fed. Cir. 1983) (emphasis added; internal citations omitted) (concluding that activities occurring after the filing of the United States patent application were “irrelevant”). *See, e.g., CFMT, Inc. v. Yieldup Int’l Corp.*, 349 F.3d 1333, 1339 (Fed. Cir. 2003) (“Reliance on the TI data alone also betrays another error, namely that this court gauges enablement at the date of the filing, not in light of later developments.”); *Phillips Petroleum Co. v. U.S. Steel Corp.*, 673 F. Supp. 1278, 1291 (D. Del. 1987), *aff’d*, 865 F.2d 1247, 1251 (Fed. Cir. 1989) (“post-filing developments in the art are irrelevant to the enablement inquiry.”)

Likewise, there is no question that Mylan was not trying to follow the teachings in Plaintiffs’ patents when developing its PEPFAR product. Accordingly, under no set of circumstances can Mylan’s PEPFAR materials from 2007 shed any light on whether ***Plaintiffs’*** patent application, filed in 2004 enable those of skill in the art in 2004 to practice the full scope of ***Plaintiffs’*** alleged invention.

In their Objections to Magistrate Judge Kaull’s Order, Plaintiffs cite two cases in a footnote as apparent support for their proposition that work conducted after the filing of the patent application can be relevant to assessing enablement.³ *See* Pls.’ Obj. Mag. J. Kaull’s Order, at n.2. However, these cases are readily distinguishable from the present case. In *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F. Supp. 2d 69, 162 (D. Mass. 2001), the district court considered post-filing publications that followed the techniques in the patent application at issue

³ It should be noted that Plaintiffs failed to cite either of these cases in their Opening Motion to Compel, in the Reply brief or at oral argument before Magistrate Judge Kaull. Indeed, Plaintiffs failed to identify ***any*** legal authority to Magistrate Judge Kaull (in their briefs or at the hearing) to support their argument that activities occurring after the filing date of the patent application at issue could somehow be relevant to the issue of enablement. It strains all credibility for Plaintiffs to contest Magistrate Judge Kaull’s Order on this aspect of patent law, when Plaintiffs failed to provide Magistrate Judge Kaull any legal support for their position. *Cf. Myers v. Reason*, 2007 WL 81891 (N.D.W. Va. 2007), at *3 (reciting general rule that contentions not raised before magistrate judge are waived, and citing case).

when assessing enablement. *See id.* (discussing a “series of post-filing publications . . . using the techniques taught in the Amgen [patent application] specification”). Unlike *Amgen*, Mylan did not use Plaintiffs’ patent application to develop its PEPFAR product. Similarly, Plaintiffs’ reliance on *Bruning v. Hirose*, 161 F.3d 681, 686 (Fed. Cir. 1998), is misplaced. There, in the context of enablement, the court permitted expert testimony relating to testing of the patent application at issue—even though the testing occurred after the filing date of the application. *See id.* However, in *Bruning*, the expert testing at issue was undertaken to test whether the application enabled the claims using techniques and equipment available as of the filing date of the application. *Id.* Here, as stated above, Mylan was not using Plaintiffs’ patent application when developing its PEPFAR product, nor have Plaintiffs alleged that Mylan’s PEPFAR product was developed using only those techniques available as of 2004.

Mylan’s later-created PEPFAR product does not relate to an assessment of whether one skilled in the art could make the product actually disclosed in the patents-in-suit, by combining the knowledge of one skilled in the art with the specific information in the patents’ disclosures. That hypothetical enablement inquiry cannot be determined by asking what Mylan did or did not do, years after the relevant time period, when developing a drug for use in other countries, under different regulatory and patent guidelines than those applicable to the instant case. Mylan’s PEPFAR product, thus, is irrelevant to the question of whether Plaintiffs’ patents are invalid for lack of enablement.

V. CONCLUSION

For the foregoing reasons, Mylan respectfully requests that the Court reject Plaintiffs' Objections to Magistrate Judge Kaull's Order.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on July 28, 2015, I filed the foregoing **DEFENDANTS MYLAN INC. AND MYLAN PHARMACEUTICALS INC.'S OPPOSITION TO PLAINTIFFS' OBJECTIONS TO MAGISTRATE JUDGE KAULL'S ORDER/OPINION DENYING MOTION TO COMPEL DOCUMENTS** with the Clerk of the Court using the CM/ECF system, which will send a notice of electronic filing to the attorneys of record for Plaintiffs Gilead Sciences, Inc. and Emory University.

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